



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880
500 7590 03/15/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER BARNHART, LORA ELIZABETH	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/763,570	Applicant(s) DRAKE ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 1/3/07 to claims 1, 5, and 7 have been entered. Claims 3, 4, 6, and 9-27 have been cancelled in this or a previous reply. Claims 1, 2, 5, 7, and 8 remain pending in the current application, of which claims 1, 2, 5, and 7 are being considered on their merits. Prior art references not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC § 112

The rejections of record under 35 U.S.C. § 112, second paragraph, are withdrawn in light of the claim amendments. The examiner notes for the record, however, that the reply was not accompanied by "a copy of the trademark search from the U.S. Patent and Trademark Office website conducted 11-20-2006," as alleged by applicant at page 4, paragraph 2, of the reply.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires that the bacteria and nutrient within the composition be "mixed and incubated prior to use," which is confusing. The claim is drawn to a composition (*i.e.*, a kit) and not to any method. It is not clear whether the "mixing" and "incubating" are actual process steps in a method of making. Furthermore, the limitation "prior to

Art Unit: 1651

use" is confusing, because the manner of "use" is not particularly pointed out and because again, the claim is drawn to a composition, not to a method of using. The claim should be amended such that the physical characteristics of the composition are particularly claimed. Clarification is required.

Because claims 2, 5, and 7 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2003, U.S. Patent 6,645,506) taken in view of Jaffe (1974, U.S. Patent 3,852,454).

Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45) and an antioxidant (column 17, lines 33-35). Farmer teaches a formulation comprising *Bacillus coagulans* and fructooligosaccharides (column 25, line 62, through column 26, line 4) and mixing said formulation into water (column 20, lines 42-53).

Farmer does not explicitly teach a composition comprising ascorbate or ascorbic acid.

Art Unit: 1651

Jaffe teaches that ascorbic acid was a well-known antioxidant at the time of the invention of Farmer.

A person of ordinary skill in the art would have had a reasonable expectation of success in including ascorbic acid in the composition of Farmer because Farmer suggests adding "known antioxidants," and Jaffe teaches that ascorbic acid was a known antioxidant at the time of the invention of Farmer. The skilled artisan would have been motivated to add ascorbic acid to the composition of Farmer because Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition (column 17, lines 21-42).

A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said composition.

The selection of probiotic bacteria to be included in the composition of Farmer clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Farmer teaches that the bacteria may be one or more of any of numerous probiotic bacteria and that the recited bacteria are art-accepted equivalents (column 2, lines 21-32). A holding of obviousness over the cited claims is therefore clearly required. The claimed subject matter fails to patentably

Art Unit: 1651

distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

While Farmer does not explicitly teach a composition comprising a mixture of probiotic bacteria, the inclusion of multiple different strains (as required in instant claim 7) does not render the instant composition patentable. Farmer specifically contemplates compositions comprising multiple strains (column 2, lines 19-22). In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacteria are art-accepted substitutes for each other. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12). It would have been further obvious for the artisan to add ascorbic acid to the composition of Farmer because Farmer teaches that the inclusion of antioxidants in bacterial compositions facilitate the growth and germination of the bacteria therein (column 17, lines 21-42).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Art Unit: 1651

Applicant alleges that there is no motivation to combine the references as set forth by the examiner (Reply, page 4, paragraph 4, through page 5, paragraph 1). Applicant alleges that the amendments to claim 1 overcome the art rejections (Reply, page 5, paragraph 2). These arguments have been fully considered, but they are not persuasive.

As discussed in a previous Office action, Farmer specifically teaches a motivation for including antioxidants in the composition, *i.e.*, facilitating the growth and germination of the bacteria within the composition (column 17, lines 21-42): "The formulation...of this invention may include other probiotic agents or nutrients for promoting spore germination and/or *Bacillus* growth...the therapeutic compositions may include, but are not limited to the inclusion of: known antioxidants."

Furthermore, even if Farmer did not explicitly suggest including antioxidants in their composition, it would have been obvious to do so. The U.S. Federal Circuit has recently explicitly stated that in order to make a *prima facie* case of obviousness, the suggestion and motivation to combine the references need not be explicitly stated in the text of the references. In *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006), the Court writes, "the suggestion test is not a rigid categorical rule. The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. *In re Dembiczak*, 175 F.3d 994, 999 [50 USPQ2d 1614] (Fed. Cir. 1999). As we explained in *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 [43 USPQ2d 1481] (Fed. Cir.

Art Unit: 1651

1997), 'there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.'" See *Dystar* at 1645. "Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense." See *Dystar* at 1650.

In this case, the expressly stated utility of the compositions of Farmer is the treatment of infections of the skin (column 7, lines 42-51, for example), and antioxidants were known in the art at the time of the invention to be useful and efficacious for treating skin infections. Grossman et al. (1991, U.S. Patent 4,986,985, reference A) teach that plant extracts provide an antioxidant effect when applied to the skin and treat viral skin infections (Abstract), and Schrauzer (1993, U.S. Patent 5,236,697; reference B) teach that at the time of the invention, it was well known that bacterial infections result in excessive amounts of oxygen radicals, which can be countered by the application of antioxidants (column 2, line 60, through column 3, line 2). The motivation to include antioxidants in the composition of Farmer can be found not only in Farmer's disclosure, but also in the common knowledge of the art and common sense of its skilled practitioners, as evidenced by the teachings of Grossman et al. and Schrauzer.

Regarding the amendments to the claims, it is submitted that the composition of Farmer is mixed and incubated; "incubating" is a broad term that merely requires maintaining a system under some conditions favorable for some level of growth of the bacteria. Since the bacteria in the composition of Farmer are viable (column 17, lines 8-

Art Unit: 1651

15 and 23028), the "incubating" limitation requires only that the composition be maintained under such conditions that the bacteria within the composition can grow; indeed, since the utility of the compositions of Farmer rely on the viability of the bacteria, the compositions are necessarily "incubated."

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

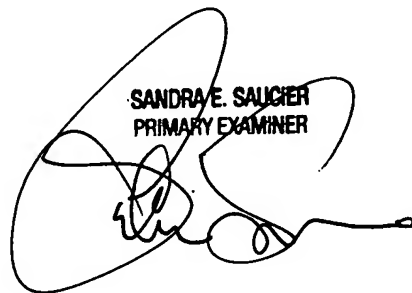
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone

Art Unit: 1651

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart



SANDRA E. SALCIER
PRIMARY EXAMINER